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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,247	07/09/2003	Philip S. Kim	126066-00101	9491
64574	7590	02/19/2009		
BLANK ROME LLP ONE LOGAN SQUARE PHILADELPHIA, PA 19103			EXAMINER STIGELL, THEODORE J	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 02/19/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/616,247

Applicant(s)

KIM, PHILIP S.

Examiner

THEODORE J. STIGELL

Art Unit

3763

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 30-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 30-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 38, 39, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The listed claims each recite a group of medication using "consisting of" language, but the groups do not have support in the originally filed disclosure. The originally filed disclosure includes other medications in the groups listed above, and therefore it is clear that the applicant did not see an advantage of using one medication over the other (ex., local anesthetics has been removed from original claim 17). If the applicant wants to use "consisting of" language, the original groups must be presented. Furthermore, there is no support for "consisting essentially of" language in the original disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-41 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. The applicant uses "comprising" language after specifically using "consisting of" language in the independent claims. Applicant is reminded that "consisting of" is closed language and cannot be broadened in independent claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-4, 14-15, 20-21, 30-33, and 36-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellinwood Jr. (3,923,060). Ellinwood discloses a method of providing long term pain management comprising the steps of surgically implanting a catheter (248) to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure, surgically implanting an implantable pump (150 or Figure 13) and a reservoir (126 or Figure 13) in subcutaneous tissue, wherein the proximal end of the catheter and the reservoir are in communication with the pump, and operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site whereby pain management is

provided for weeks, months, or years, wherein the catheter is lined with a metal strip (251) conductive to electricity. Ellinwood's disclosure from column 6, line 15- column 8, line 9 discloses multiple examples of implanting a catheter in peripheral neural structures and column 7, lines 15-22 indicates that pain management is one of the applications Ellinwood contemplated.

Claims 1, 3-4, 14-15, 20-21, 30-33, and 36-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Mann et al. (6,941,171). Mann discloses a method of providing long term pain management comprising the steps of surgically implanting a catheter (80) to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure (at least pudendal and sacral nerve stimulation are contemplated), surgically implanting an implantable pump (100) and a reservoir (inside of 100) in subcutaneous tissue, wherein the proximal end of the catheter and the reservoir are in communication with the pump, and operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site whereby pain management is provided for weeks, months, or years, wherein the catheter is lined with a metal strip (72) conductive to electricity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 5-13, 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood Jr. (3,923,060) or Mann et al. (6,941,171). Ellinwood and Mann disclose methods of pain management including all of the limitations recited in the independent claims but fail to specifically teach implanting the catheter in the nerves recited in the claims above. The examiner maintains, however, that these limitations are matters of design choice as the applicant has not shown that specifically implanting to any of these sites works better than any other site. In fact, the applicant seems to concede that the novelty of the invention is the implantation to any peripheral nerve rather than to the recited nerves (see paragraph [0060] of applicant's specification). One skilled in the art would recognize that Ellinwood's and Mann's disclosure would apply to any peripheral nerve structure.

Claims 16, 17, 34, 35, and 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood Jr. (3,923,060) or Mann et al. (6,941,171). Ellinwood and Mann disclose all of the limitations recited in the independent claim but fail to teach using the recited medications. The type of medication is deemed to be a matter of design choice. Therefore, it would have been obvious to one of ordinary skill in the art

at the time of the invention to modify to method of Mann or Ellinwood with the recited drugs to provide a better treatment of pain relief.

Response to Arguments

Applicant's arguments filed 12/5/2007 have been fully considered but they are not persuasive.

Ellinwood (Jr. (3,923,060))

In response to the applicant's argument that Ellinwood does not disclose a device that is completely implanted in the body, the examiner respectfully disagrees. Ellinwood specifically teaches (see at least the abstract) that the device is "adapted to be entirely implanted and to dispense such substances over a long period of time". One of ordinary skill would understand that the external trigger could be a wireless trigger which would still allow the pumping device to be completely implanted.

Gelfand (US 2005/0192638)

This rejection has been withdrawn and therefore the arguments are moot.

Mann (6,941,171)

In response to the applicant's argument that Mann does not disclose a method for long term pain management, the examiner respectfully disagrees. The device of Mann is designed to be implanted within the body. One of ordinary skill in the art would understand that this type of measure would not be taken to treat an intermittent condition. Furthermore, Mann specifically references treating chronic pain (see at least column 9, lines 38-40, column 10, lines 7-11, column 10, lines 18-22, column 10, line 65-column 11, line 19).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **THEODORE J. STIGELL** whose telephone number is (571)272-8759. The examiner can normally be reached on **M-F 8:30-5:00**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/

Examiner, Art Unit 3763

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763

